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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/603,024	06/23/00	POMPEJUS M	BGI-131CP

000959
LAHIVE & COCKFIELD
28 STATE STREET
BOSTON MA 02109

HM12/0720

EXAMINER	
FRIEDMAN, J	
ART UNIT	**PAPER NUMBER**
1655	6

DATE MAILED: 07/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/603,024	Applicant(s) Pompejus et al
	Examiner Jeffrey Fredman	Art Unit 1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-38* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Sequence Rules

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached CRF problem report. Compliance with the sequence rules is required and any defective response will be deemed non-responsive (bona fide attempt).

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16 and 36-38, drawn to nucleic acids, vectors and host cells, classified in class 536, subclass 23.1.

II. Claims 17, drawn to method of producing a protein, classified in class 435, subclass 69.1.

III. Claims 18-24, drawn to isolated polypeptides, classified in class 530, subclass 350.

IV. Claims 25-34, drawn to methods of producing chemicals by culturing, classified in class 435, subclass 41.

V. Claim 35, drawn to methods of diagnosis, classified in class 435, subclass 6.

3. The inventions are distinct, each from the other because of the following reasons:

4. Inventions in Group I and in Groups II, IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acids and host cells can be used in the protein production method of Group II, in chemical production methods of Group IV, in diagnostic methods of Group V, or in nucleic acid purification methods, in amplification methods, or in antisense treatment methods.

5. Inventions in Group I and in Group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the nucleic acids and the proteins differ in function, in chemical structure, in effect and are used in different methods and are produced using different methods.

6. Inventions in Groups II, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because each method has a different mode of operation with a different result. The diagnostic method results in detection of a microorganism while the chemical production method results in production of a chemical and the protein expression method results in a protein.

7. Inventions in Group II and in Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the protein can be made by the isolation method of Group II or by chemical synthesis or by in vitro protein synthesis.

8. Inventions in Groups III and in Groups IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the protein of Group III is entirely unrelated in function and effect to the diagnostic method of Group V or to the chemical production method of Group IV.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

10. This application contains claims directed to the following patentably distinct species of the claimed invention: .

Each of Groups I, III, IV or V above are generic to a plurality of disclosed patentably distinct groups each groups consisting of a different nucleic acid sequence. Applicant is required under 35 U.S.C. 121 to elect no more than one (1) disclosed sequence which cannot represent

more than 1 different SEQ ID NOs even though this requirement is traversed. Whichever Group of Groups I-V is selected above, a separate selection is required for search of One single nucleotide sequence which will be searched for the group. Applicant should note that the generic claims will be examined in light of the one specific SEQ ID Nos selected.

This requirement is based upon the notice in the Official Gazette in October 1996.

Should applicant traverse on the ground that some or all of the different nucleic acid sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. A telephone call was made to Elizabeth Hanley on July 19, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff Fredman, Ph.D. whose telephone number is (703) 308-6568.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

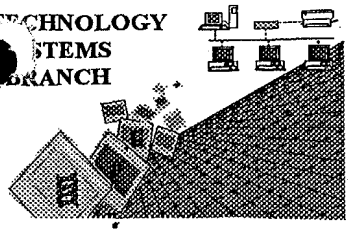
Papers related to this application may be submitted to Group 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Group 1800 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Jeffrey Fredman
Primary Patent Examiner
Art Unit 1655

July 19, 2001

OIPE

BIOTECHNOLOGY SYSTEMS BRANCH



0250

CRF Problem Report

The Scientific and Technical Information Center (STIC) experienced a problem when processing the following computer readable form (CRF):

Application Serial Number: 09/603,024

Filing Date: 6/23/2000

Date Processed by STIC: 6/30/2000

STIC Contact: **Mark Spencer, 703-308-4212**

Nature of Problem:

The CRF (was):

____ (circle one) Damaged or Unreadable (for Unreadable, see attached)

____ Blank (no files on CRF) (see attached)

____ Empty file (filename present, but no bytes in file) (see attached)

____ Virus-infected. Virus name: _____ The STIC will not process the CRF.

____ Not saved in ASCII text

____ Sequence Listing was embedded in the file. According to Sequence Rules, submitted file should **only** be the Sequence Listing.

____ Did not contain a Sequence Listing. (see attached sample)

J Other:
ZIP disk submitted; is not among acceptable CRF (computer readable form) formats, Rev 1.824 of Next an old Sequence Rules

PLEASE USE THE CHECKER VERSION 3.0 PROGRAM TO REDUCE ERRORS. SEE BELOW FOR DETAILS:

Checker Version 3.0

The Checker Version 3.0 application is a state-of-the-art Windows based software program employing a logical and intuitive user-interface to check whether a sequence listing is in compliance with format and content rules. Checker Version 3.0 works for sequence listings generated for the original version of 37 CFR §§1.821 – 1.825 effective October 1, 1990 (old rules) and the revised version (new rules) effective July 1, 1998 as well as World Intellectual Property Organization (WIPO) Standard ST.25.
Checker Version 3.0 replaces the previous DOS-based version of Checker, and is Y2K-compliant. Checker allows public users to check sequence listings in Computer Readable form (CRF) before submitting them to the United States Patent and Trademark Office (USPTO). Use of Checker prior to filing the sequence listing is expected to result in fewer errored sequence listings, thus saving time and money.

Checker Version 3.0 can be down loaded from the USPTO website at the following address:

http://www.uspto.gov/web/offices/pac/checker